REMARKS

After a detailed study of Examiner's rejection of the claims and the references cited as grounds for the rejections, applicant is submitting claims 16, 19 and 20, as amended, for reconsideration for the reasons as stated in the attached Remarks.

There is no teaching or disclosure in the prior art of record of a process for testing a urine sample for a drug of abuse in which a test card is longitudinally positioned in a container and then contacting the urine sample with the sample receiving portion of a test strip through an opening in the front face of the flat member in which the test strip is mounted.

May(WO 88/08534) does not show a sample receiving portion of a test strip exposed through an opening in the front face of the carrier or body portion. In Figs. 1-5 of May the lower end 11 of the test strip is contacted by a liquid sample.(page 16, lines 11-13). The test strip extends from the bottom end 33 of the body 30 such that the lower end 17 of the test strip is at the bottom end 33 of the body as shown in Figs. 4 and 5. The test result is visible to the user through window 32.(page 20, lines 30-32.) In Figs. 6 and 7 the bottom end 207 of the test strip 206 contacts the liquid sample in the receptacle 202 through a lateral aperture 213 in the receptacle 202 at the bottom end 201 of the device. An analyte

presence is detected in zone 209 and a control is in zone 210--both results being visible through windows 204 and 205, respectively.

In Figs. 8 and 9 of May, the test strip 510 is enclosed completely within the housing 500. Extending beyond the end 505 is a porous member 506. Within the housing porous member 506 overlaps test strip 510 such that a liquid sample applied to member 506 can permeate member 506 and progress into strip 510. Test results are reviewed through the apertures 508 and 509 in the upper face 507 of housing 500.

In Figs. 11 and 12, the test strip 606 is contained within casing 600 and has one end in contact with a porous receiving member 605. The test sample is applied through aperture 601 to permeate the test strip and the test result can be observed through apertures 603 and 604,. The sample receiving portion of the test strip is <u>not</u> exposed through any opening in the casing but receives the test sample from the porous member 605.

In Figs. 13 and 14, the end of the test strip 705 communicates with the exterior of the casing 700 through an aperture 704 in the end wall 703 of the casing. The test result is viewed through aperture 702 in the upper surface 701 of the casing 700.

It is to be noted that in the embodiments in Figs. 1-5, 6-7

and 13-14 of May, the sample receiving portion of the test strip communicates with the exterior of the housing only at the extreme tip end of the test strip. There is no teaching in any of the embodiments of May of exposing the sample receiving portion of the test strip through an opening in the front face of the housing.

Exposing a large flat area of the sample receiving portion of the test strip to directly contact the test sample as disclosed by applicant, will enable a greater quantity of the sample to be more quickly delivered to the test strip which results in greatly reducing the time required for the test.

An end edge of a test strip is a relatively small area of the test strip and exposing such an end edge to a test sample(May Fig. 5 and Fig. 14) will cause a very slow wicking up of the test sample through the test strip to contact the analyte testing zone. Further, this exposure of the end edge of the test strip would make this end edge extremely vulnerable to damage or deformation by any concontact of the end edge with a foreign object. Any such damage or deformation will seriously impair the flow of test sample into the test strip.

On the other hand, applicant not only protects the end edges of the test strip by spacing these end edges from the top and bottom of the test card and enclosing the test strip between the front and rear surfaces of the test card. At the same time,

applicant exposes the flat surface area of the sample receiving portion of the test through an opening in the front surface of the test card to enable this portion of the test strip to directly contact the fluid test sample.

Sun et al (5,238,652) also does not teach a test strip enclosed in a thin flat member such that the sample receiving portion of the test strip is exposed through an opening in the front surface of the flat member to directly contact a fluid test sample when the flat member is inserted into a sample container. In the embodiment of Figs. 1a and 1b, a fluid sample is introduced into the reception cavity 107 and flows through a passage channel 108 onto the test strip 102. The passage channel 108 has a coarse surface to prevent the free flow of the sample toward the test strip until a vacuum pulling action is initiated to commence flow. (col. 7, lines 17-21) In the embodiment of Figs. 2a-2h, there is a reception cavity 203 having an opening 204 but there is no showing or teaching of any relationship of a test strip and the the reception cavity opening 204. Bottom half 205 of the device receives the test strip (col. 8, lines 3-4) and in"Fig 2f, the sample well is inclined such that it slopes into the membrand chamber." (col.8, lines 10-11) but there is no clear showing of

such a chamber or a test strip.

Sun is not concerned with direct contact of the test sample with the sample receiving portion of the test strip but seeks to achieve a slow controlled flow of the sample to the test strip (see col. 8, line 9 and lines 14-25). In the embodiment of Figs. 4a - 4k, note that "When a liquid sample is deposited in the opening 401, the aqueous solution percolates through the absorbing or filter 402 on to and down the membrane....." (col.8, lines 56 - 59)

Boger has nothing to do with lateral flow immunoassay test strips but discloses a test device holder 10 which supports a number of strip test devices 20 each of which has a number of chemical reagent pads spaced on a surface of each strip test device to correspond with openings 18 in the holder. Each reagent pad extends upwardly from the surface of a test device and these reagent test pads are exposed through the openings in the holder (col.5, lines 39-40). These reagent pads are dip-and-read test devices which are wholly dissimilar from lateral flow immunoassay test strips. In a chemical reagent test pad the sample flows through the pad perpendicularly to the membrane or strip upon which the pad is mounted and the results of the test are read on the same area of the pad to which the sample was applied, whereas in

an immunoassay test strip the sample flows laterally within the strip from a sample receiving zone to a reaction zone on the strip spaced from the sample receiving zone.

If the Boger chemical reagent test pad is used for immunochemical testing as he suggests, then either reagents must be added to the test pad at the same area where the sample is applied and where the test results are to be read, or the reagents may be stacked or layered upon each other in the test pad. However, Boger teaches that the test results are read at the same area where the sample is applied. Such a reading would be very difficult, if not impossible, since the results would be at the bottom layer of reagents which is not visible at the top of the test pad.

Boger's test device holder is further very different from the applicant's test card in that in Boger a plurality of openings 18 are arranged so that an individual reagent pad is positioned in each opening. The sample to be tested is then applied individually to each reagent pad or the entire holder is dipped into the sample to be tested. The results of the test are then read by inserting the holder with the test device and pads thereon into an instrument ("automated photometric apparatus"). Boger does not teach reading of the test results directly from the test strip in the holder

and, accordingly, there is no disclosure or suggestion of openings in the holder to view the test results at regions on the holder different than the sample receiving pads since the results of his tests are read directly from each reagent pad when it is inserted in a suitable apparatus.

Applicant's invention differs significantly from the approach in Boger in that applicant discloses a holder for lateral flow immunoassay test strips in which the sample to be tested is applied through an opening in the front surface of the test card to one portion of the test strip and the visual result of the test is viewed through another opening in the front surface exposing the detection portion of the test strip.

Basically, Boger is concerned with mounting of chemical reagent pads while applicant's invention is directed to the mounting of lateral flow immunoassay test strips.

Huang et al (5, 712,172) discloses an immunoassay test strip having a sample receiving region which is placed within a flowing stream of sample liquid (i.e.) urine stream) but the test strip is "without a plastic housing". A plastic strip, preferably "clear mylar" covers the top surface of the test strip for added strength, but exposes portions of the sample receiving region.

The patentee emphasizes that the test strip device is without a plastic casing.

Each of the remaining references of record have been closely studied in view of Examiner's remarks with respect thereto, but none of these references taken either singly or in combinations as proposed by Examiner, would provide any basis for rejection of applicant's claims.

Lee-Own et al (5,500,375) also discloses that the test sample enters through the end of the test strip which is exposed only after the test device is cut at 16 (see col. 7, lines 53-62). Neither Galloway (5,403,551) nor Davis (5,119,830) disclose positioning a test card longitudinally into the open top of a container having the test sample therein.

In summary, none of the cited references taken either singly or in combination, teach conducting a drug of abuse test by longitudinally positioning a test card in a test container and then contacting the sample to the sample receiving portion of a test strip through an opening in the front face of the flat member enclosing the test strip.

With respect to the rejection of claims 16-20 as being unpatentable over claims 1-6 in U.S. Pat. 5,976,895, it is pointed out that claim 16 recites steps of "contacting the urine sample with the

sample receiving portion" of a test strip and "moving the urine sample within a test strip by capillary action to the test portion,..." Neither of these steps are set forth in independent claim 1 of the afore-mentioned patent.

The rejection of claims 16-20 as being unpatentable over claims 16-30 of co-pending Application No. 10/153,205 should be withdrawn since this application is being abandoned.

A terminal disclaimer will be timely filed in the event any allowed claims are deemed to conflict with any commonly owned application or patent.

In view of the foregoing remarks discussing the inadequacies of the cited references when taken either singly or in combination, it is believed that independent claim 16 and claims 19, 20 depending therefrom are patentable over the prior art. An early and favorable response is respectfully requested.

A Petition for Extension of Time together with the requisite fee is attached to the paper.

Respectfully submitted

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